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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,307	07/18/2000	Clements C. Lambeth	WEYE115226	9512

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/02/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/618,307

Applicant(s)

Lambeth et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

10/15/02

- ☒ Responsive to communication(s) filed on _____.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above claim(s) 1-19 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4, 5
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1638

Applicant's election with traverse of Group II in Paper No.10 is acknowledged. The traversal is on the ground(s) that Group I encompasses Group II, and that the species election regarding molecular markers in Group I was incorrect because one of ordinary skill in the art could utilize each type of marker. This is not found persuasive because Group I requires plant species and molecular markers not required by Group II, while Group II requires plant species not required by Group I, as stated previously. Regarding the molecular markers, the Examiner maintains that each type of marker would require a different search by the Examiner, regardless of the level of skill of the ordinary artisan.

The requirement is still deemed proper and is therefore made FINAL.

The specification is objected to for its inclusion of an active hyperlink on page 25, line 12. Internet retrieval of any patent issued from the instant specification would result in the incorporation of a live web link within the text of the patent. Since the U.S. Patent and Trademark Office exercises no control over any commercial organization accessible by said hyperlink, USPTO policy does not permit the PTO to link to any commercial sites. Applicants are requested to delete the hyperlink on page 25, line 12.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

Art Unit: 1638

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to a method of using a multitude of non-exemplified DNA markers from a multitude of taxonomically unrelated and physiologically and genetically divergent tree species including oak, pine, palm, ginkgo and orange; which markers would include RFLPs, AFLPs, RAPDs, SSRs, SSR-anchored PCR-derived markers, SNPs, SSCPs, SCARs, STSs, ASAPs, SPARs and CAPs. In contrast, the specification only provides guidance for SSRs from a single coniferous species, *Pinus taeda*. No guidance is provided for the isolation or characterization of DNA from any other tree species, or for the obtention and characterization of any other type of DNA marker from any tree species.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Art Unit: 1638

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991), where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is broadly drawn to a method of using a multitude of non-exemplified DNA markers from a multitude of taxonomically unrelated and physiologically and genetically divergent

Art Unit: 1638

tree species including oak, pine, palm, ginkgo and orange; which markers would include RFLPs, AFLPs, RAPDs, SSRs, SSR-anchored PCR-derived markers, SNPs, SSCPs, SCARs, STSs, ASAPs, SPARs and CAPs; wherein said method comprises performing polymix-mediated pollination of a group of trees, and then utilizing said markers to determine the pedigree of progeny trees following their phenotypic scoring.

In contrast, the specification only provides guidance for SSRs from a single coniferous species, *Pinus taeda*. No guidance is provided for the isolation or characterization of DNA from any other tree species, or for the obtention and characterization of any other type of DNA marker from any tree species. In addition, no guidance is provided for determining actual pedigrees or phenotypes of the progenies. Only preliminary data regarding the overall relatedness of different categories of plants, such as grandparents, parents, offspring, full- and half-sibs, are provided. No guidance is provided for any further pedigree determination of individual plants. In addition, no guidance is provided for scoring the progeny for any phenotype or for selecting elite trees from the progeny.

Polymix-mediated breeding of trees for phenotypic change is unpredictable, given the lack of available knowledge regarding flower biology or pollination control in many tree species (see, e.g., White, page 113, column 1, second paragraph). In addition, environmental effects on trait expression may confound the selection of desirable progeny which should possess heritable genetic components conferring the phenotypic change (see, e.g., Stoehr et al, 1998, Canadian Journal of Forest Research, Vol. 28, No. 3, pages 418-426, particularly the Abstract).

Art Unit: 1638

Furthermore, the use of polymix breeding may be confounded by the unequal reproductive success of many parents' pollen, so that the genetic contribution would be less diverse than planned, and which would also lead to incorrect measurements of general combining ability (see, e.g., Wiseloge et al, page 187, column 2, first full paragraph). See, e.g., Rogers et al (page 374, Table 3 and column 2; page 375, column 1; page 376, Table 6; paragraph bridging pages 376 and 377; page 377, Figure 2) who teach this phenomenon in black spruce. See also Moran et al, page 117, Abstract, who teach this phenomenon in *Pinus radiata*. Apparently only the exemplified *P. taeda* is exempt from this phenomenon (see, e.g., Wiseloge et al, page 184, column 2; page 187, column 2, top paragraph).

Molecular marker-mediated selection in tree breeding, particularly in open-pollinated schemes such as polymix breeding, is unpredictable. See, e.g., Strauss et al, page 1050, Abstract, who teach that molecular markers are of limited availability and of high cost, are restricted to particular genetic backgrounds, and that many traits of interest to tree breeders are highly environmentally influenced, which would interfere with selection of phenotypes to which markers could be reliably assigned. Strauss et al also teach that molecular markers are more useful in controlled hybrid breeding schemes or full-sib families (see, e.g., Abstract), rather than the instantly claimed polymix breeding where mixtures of several parents' pollen are utilized in a half-sib scheme. In addition, linkage equilibrium will confound trait-marker associations (see, e.g., page 1052, column 2, penultimate paragraph; page 1053, column 1, second full paragraph). See

Art Unit: 1638

also page 1053, column 2; paragraph bridging pages 1053 and 1054; page 1054, column 2, third and fourth full paragraphs; paragraph bridging pages 1054 and 1055.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified markers from the exemplified tree species or from a multitude of non-exemplified tree species, to develop and evaluate progeny phenotype scoring systems in a multitude of tree species and for a multitude of phenotypes, to utilize polymix breeding to obtain selectable phenotypic change in a multitude of exemplified or non-exemplified tree species for a multitude of non-exemplified traits, or to utilize a multitude of exemplified or non-exemplified DNA markers to identify the pedigree of a multitude of exemplified or non-exemplified progeny from a multitude of exemplified or non-exemplified tree species and polymix-generated progeny.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

Art Unit: 1638

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bridgwater in view of El-Kassaby et al and Stoehr et al (1998, Canadian Journal of Forestry Research, Vol. 28, pages 187-195).

The claim is broadly drawn to a method of breeding any tree species, comprising utilizing polymix pollination of each pollen source individually, scoring progeny trees for a particular phenotype of interest, determining the pedigree of the progeny via DNA analysis, and selecting elite trees for further breeding.

Bridgwater teaches the advantages of polymix-mediated tree breeding regarding selection for particular phenotypes such as resistance to rust disease, general combining ability, and gains in additive genetic variation; wherein one type of polymix scheme is complete nesting involving the use of all pollen parents as females; and wherein the scheme generally costs less than other breeding schemes such as diallel crossing (see, e.g., pages 74-76).

Bridgwater do not teach the use of molecular markers to determine pedigree.

El-Kassaby et al teach the use of molecular markers such as isozymes to determine the pedigree of progeny from a polymix cross of Douglas fir trees (see, e.g., page 753, column 1, bottom two paragraphs; column 2, Table 1 and first two full paragraphs; paragraph bridging pages 754 and 755; page 755; page 756, Table 6 and column 2, second and third full paragraphs).

Art Unit: 1638

Stoehr et al teach the use of DNA markers to identify pedigree in Douglas fir, wherein the technique has many advantages including increased accuracy and resolution over other markers such as isozymes (see, e.g., page 187, Abstract; page 188, column 1, second full paragraph; page 193, column 1, first full paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the method of polymix tree breeding taught by Bridgwater, and to modify that method by utilizing the pedigree analysis step in the Douglas fir polymix breeding program taught by El-Kassaby et al, and to further modify that method by utilizing the DNA marker taught by Stoehr et al, as suggested by each reference; given the recognition by those of ordinary skill in the art that each would have continued to function in its known and expected manner.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 26, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

